CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.			
Typed or Printed Name	PAMELA SHERWOOD		
Signature	Pamela Sherwood	Date	12/26/2002

REQUEST FOR DECLARATION OF INTERFERENCE, 37 C.F.R. §1.607/608(a)	Attorney Docket	CELL-004CON
	First Named Inventor	Henderson
	Application Number	09/732,169
	Filing Date	December 6, 2000
	Group Art Unit	1633
Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Examiner Name	B. Whiteman
	Title: *Tissue Specific Adenoviral Vectors*	

Sir:

Pursuant to the provisions of 37 C.F.R. §1.607 and 37 C.F.R. §1.608(a), Applicants request declaration of an interference between the above-captioned patent application and an unexpired patent. The requirements of 37 C.F.R. §1.607 are met, below, *seriatim*:

1. Applicants request declaration of an interference with U.S. Patent 5,998,205.

2. As a proposed count, Applicants advance Claim 77 of the above-captioned patent application, Claim 78, Claim 79 or Claim 80, OR Claim 1, Claim 5, Claim 12 or Claim 18 of U.S. Patent 5,998,205 (hereinafter "'205 patent"). Alternative counts of this type, sometimes refer to as "McKelvey Counts" are commonly employed by the Board of Patent Appeals and Interferences, Trial Board.

3. Claims 1-20 of U.S. Patent 5,998,205 correspond to the count, Claims 1, 5, 12 and 18 corresponding identically.

4. Claims 77-80 of the above-captioned patent application correspond to the proposed count identically. Claims 61 - 67 also correspond to the proposed Count.

5. This provision of Rule 607 is inapplicable. Claims 77-80 were advanced with the Amendment dated May 29, 2002. The Examiner has already considered and treated these claims in the Office Action of August 27, 2002. No rejection for lack of support was made in any way.

6. The requirements of 35 U.S.C. §135(b) are satisfied. The above-captioned pending application is a continuation application of U.S. Patent Application Serial No. 09/151,376, filed

September 10, 1998, thus prior to the anniversary date of the '205 patent. The parent '376 application was filed with fifty-four (54) original claims, some of which are directed to the same, or substantially the same subject matter as the claims of the '205 patent. A comparison between Claim 1 of the '205 and the original claims of parent application U.S. Patent Application Serial No. 09/151,376 is appropriate. Thus, Claim 1 of the '205 patent has three essential limitations. It must be directed to (1) an adenovirus vector which, by reason of having a (2) gene that is essential for the replication of the vector (E1a, E1b, E2 and E4) under the control of a (3) heterologous tissue-specific transcriptional regulatory sequence, is tissue-specific replication-conditional.

Claim 4 of the original U.S. Patent Application Serial No. 09/151,376 is directed to an adenovirus vector, wherein the vector has a gene essential for replication (Claim 3) which is E1A, under the control of a cell type-specific transcriptional response element. It is clear from the description of transcriptional initiation region, also describes as transcriptional regulatory, or response, element, TRE, which appears on page 23, lines 16-21 of the application that this is identical to "transcriptional regulatory sequence," of the '205 patent, noting in particular that page 5, lines 23-26, describes the TRE as replacing the promoter for the early gene placed under its control. Consistent with the '205 patent, early genes are described as including E1a, E1b, E2, and E4 (page 24, lines7-8). That the resulting cells are replication-conditional in a cell-type specific manner is made clear in the specification, beginning at page 10, which describes the transcriptional regulatory element or TRE is tissue-specific, with preferential replication in particular target cells. TRE is defined on page 12, line 26 - page 13, line 6 as comprising an enhancer or promoter element, which is identical to the definition for transcriptional regulatory sequence in the '205 patent, see Claim 2 thereof. The TRE sequences that are described at page 14, line 26 of the application - page 16 make it clear that the TRE is heterologous, that is, activation of the promoter or enhancer element is from a source other than the adenoviral vector. See also original Claims 21 and 27.

Applicants further note that Claim 51 of the original filed application is directed to subject matter that is identical to that of Claim 4 of the '205 patent. Accordingly, the requirements of 35 U.S.C. §135(b) are met.

37 CFR § 1.608(a)

Applicants advance this request for declaration of interference pursuant to the provisions of either Rule 607 or Rule 608(a), because of the uncertainty of the effective filing date to which the '205 patent is entitled. Applicants are entitled to an effective filing date for the claims in question of U.S. Patent Application Serial No. 08/495,034, filed June 27, 1995, now U.S. Patent 4,698,443. The '205 patent was filed November 28, 1995, after Applicants effective filing date, claiming priority of a

CIP parent, U.S. Patent Application Serial No. 08/487,992, filed June 7, 1995, abandoned, which in turn claims priority of a CIP application U.S. Patent Application Serial No. 08/348,258, filed November 28, 1994. It is clear that the effective filing date for the claims of the '205 patent can be no earlier than the June 7, 1995 filing. Even the concept of the claims, that is, tissue-specific replication-conditional adenoviruses and related cell lines is missing from this earlier 1994 filing, which is confined to replication-deficient vectors. The vectors of the 1994 filing are directed to "deletion vectors," that is, vectors wherein a function of a gene essential for viral replication has been eliminated, typically by DNA deletion or manipulation. See in general, page 9, which specifies that the vectors are complemented by the endogenous host cell line, and not activated by factors impacting a promoter or enhancer. Applicants are of the opinion that similarly, support for the claims of the '205 patent do not appear in the June 27, 1995 filing, U.S. Patent Application Serial No. 08/487,992. Applicants note, in particular, the reliance during prosecution of the '205 patent on specific disclosures in the Amendments of October 13, 1998 and May 21, 1999. These disclosures are found only in the application as filed on November 28, 1995.

Nonetheless, Applicants note that detailed consideration of this issue is unnecessary, as even if the '205 patent were, for the purposes of argument, considered to have an effective filing date of the June 7, 1995 filing date, that filing date is within three months of Applicants' own filing date of June 27, 1995. As, pursuant to the provisions of 37 C.F.R. §1.608(a) Applicants specifically state that there is a basis upon which they are entitled to judgment relative to the '205 patentees, and an interference should be declared.

Examination of this application with special dispatch, pursuant to the provisions of Rule 607(b) is respectfully requested. The Examiner is invited to contact undersigned counsel at the Examiner's earliest opportunity, if there are any questions regarding this matter.

The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number CELL-004CON.

Respectfully submitted,

Date: 12/26/2002

By: Pamela Sherwood
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket	CELL-004CON
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Examiner Name	B. Whiteman

Title: Tissue Specific Adenoviral Vectors

DECLARATION UNDER 37 C.F.R. 1.131

Assistant Commissioner for Patents
Washington D.C. 20231

This Declaration with the attached Exhibits are being submitted in conjunction with the Applicants' Response to the Office Action dated August 27, 2002.

We, Daniel Henderson and Eric Shuur, being duly sworn, declare that:

We are the joint inventors of the subject matter described and claimed in the above-captioned patent application. We have read and understand the Office Action of August 27, 2002 and the references cited by the Examiner, including U.S. Patent Application no. US2001/0053768, claiming priority to U.S. Patent application no. 08/433,798, filed May 3, 1995, herein referred to as the Gregory application.

Prior to May 3, 1995 (the priority date of the Gregory application), we had formulated the conception of a tissue-specific replication-conditional adenovirus vector comprising a heterologous tissue-specific transcriptional regulatory sequence operably linked to the coding region of a gene that is essential for the replication of said vector, and the use of such a vector for the selective cytolysis of target cells. Evidence is provided by Exhibits A, B, C, D, E and F. All redacted dates are prior to May 3, 1995.

Exhibit A consists of signed laboratory notebook pages from D. Henderson, describing the conception of a "tissue-specific virus". The virus would "drive E1A with PSE [prostate specific enhancer]", and could be grown in cells to create "replication competent virus".

Exhibit B consists of signed laboratory notebook pages from D. Henderson, describing the genetic construction that would be used to create the tissue specific adenovirus. The hand-drawn figure shows the restriction sites, coding regions, and regulatory elements that are in the tissue specific virus.

Exhibit C consists of signed laboratory notebook pages from D. Henderson, showing the results of restrictions digestions, and ligations, providing detailed examples of specific reporter constructs.

Exhibit D consists of signed laboratory notebook pages from D. Henderson describing strategies for construction of the constructs, by moving in the reporter genes and performing PCR on the minimal enhancer then moving in the enhancer by way of a second cloning step.

Exhibit E consists of signed laboratory notebook pages from D. Henderson, and from Gail Henderson, who was working under his direction. Included is an agenda for adenovirus constructs, and description for the construction of adenovirus constructs. The exhibit also shows diagrams of constructs in progress.

Exhibit F consists of signed laboratory notebook pages from D. Henderson describing strategies for synthesizing oligos to be used in PCR, and an updated agenda for adenovirus constructs.

From May 3, 1995 until Applicants claimed priority date of June 27, 1995, Applicants were diligent towards reducing the invention to practice, as evidenced by the attached exhibits.

Exhibit G consists of signed laboratory notebook pages from Gail Henderson, describing the growth of plasmids containing elements used in the final virus construct, the verification of structures by restriction digestion. The notebook pages are dated May 8, 1995, May 17, 1995 and May 18, 1995.

Exhibit H consists of a letter sent by Applicants' patent counsel dated June 23, 1995, in which a draft application of the patent application was enclosed.

Applicants respectfully submit that the invention set forth in the present application was conceived prior to the effective priority date of the Gregory application, U.S. Patent Application no. US2001/0053768. Applicants were diligent in reducing the invention to practice from the conception date, to the date of filing of priority application 08/495,034, on June 27, 1995.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: _____ _____

Daniel Henderson

Date: _____ _____

Eric Shuur

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: _____ _____

Daniel Henderson

Date: _____ _____

Eric Shuur